

REMARKS

By this amendment, Claims 1, 7-10, 12-14, 17, and 20 are currently amended, and Claims 2-6, 11, 15-16, and 18-19 remain as originally presented.

The above-identified Office Action has been reviewed and the references carefully considered. In view hereof, the present amendment is submitted. It is contended that by the present amendment all bases of rejection set forth in the Office Action are traversed and overcome. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The Examiner's rejections will be addressed in the order presented in the Detail Action section of the Office Action.

Claim Rejections 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-3, 6-7, 9-10, 13, 15-17, and 19 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,203,769 to Clement et al. Section 102(b) states that a person shall not be entitled to a patent when:

the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant traverses the Examiner's rejection. Under 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element *as set forth in the claim* is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *See* MPEP 2131 (emphasis added). The U.S. Court of Appeals for the Federal Circuit has firmly established that anticipation only occurs when the elements found in a single prior art reference are "arranged as in the

claim.” *Structural Rubber Prods. Co. v. Park Rubber Co.*, 223 USPQ 1264, 1271 (Fed. Cir. 1984); *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, a single prior art reference does not anticipate a claim when the rejection is based upon non-overlapping embodiments disclosed within the reference.

Applicant respectfully submits that Clement does not disclose each and every element required by the claims of Applicant’s invention. Accordingly, Clement fails as a reference upon which to predicate an anticipation rejection and submits that the Examiner’s rejection under § 102 should be withdrawn.

Regarding Claim 1, the Examiner has rejected Claim 1 based upon the embodiment shown in FIG. 15 as well as disclosure in the written description directed towards the proximal end of the tubular structure and the valve.

The Applicant notes that the embodiment of Clement shown in FIG. 15, which is a side view of FIG. 14, includes a valve mechanism having a dual valve/conduit construction to allow both the entry and exit of fluids from a patient’s ear, as more fully discussed below. It is specifically designed to be a single device which is intended to be more compact, practical, and user-friendly than two separate devices during medical procedures. The specific purpose of this device is to both deliver and remove fluid from the patient.

Conversely, the claimed invention in the present application is a single passageway device which is designed for removing foreign objects from body cavities through negative pressure. The present invention operates by the cooperation between the enveloping lips and suction capacity. The enveloping lips of the tubular element or structure envelop a foreign object. The frusto-conically shaped distal end has enveloping lips which are

designed to envelop and seal around a foreign object lodged within a body cavity. Suction is applied, thus trapping the foreign object against the enveloping lips. The foreign object is then removed from the cavity.

There are several fundamental differences between the claimed subject matter of the present invention and Clement. Clement serves to deliver and remove fluids, while the present invention is designed to envelop foreign objects and remove them via suction. As a result, Clement does not disclose several elements required in the claims, as is discussed below. Furthermore, because of the entirely separate function of the present invention and Clement, it would not have been obvious to one of ordinary skill in the art to modify Clement to supply the missing elements required by the claims.

In an effort to expedite and facilitate prosecution, and acting without prejudice, the Applicant has amended Claim 1. The currently amended Claim 1 now more clearly defines that the frusto-conical end portion is oriented so that: it is “flaring outwardly at the distal end”; the distal end includes an “annular enveloping lip”; and the tubular structure defines a single passageway.

As to the frusto-conical end, the Examiner has cited FIG. 15 of Clement as teaching such an element. The Applicant respectfully disagrees. The distal end in FIG. 15 is not “generally frusto-conically shaped” as required by Claim 1. As seen in FIG. 15, the conduit *appears* to expand in cross-sectional area as it approaches the distal end. However, as shown clearly by both FIG. 14 and description of the drawings, this is only an optical illusion, and the distal end in FIG. 15 is not generally frusto-conically shaped. FIG. 14 is a top view of FIG. 15 (col. 3, lines 3-5). FIG. 14 clearly shows that the conduit maintains its

cross-sectional area along the entire length of the structure. In addition, the conduit shown in FIGS. 14 and 15 is “configured to curve sideways *and downward* with respect to the valve body” (col. 3, lines 5-7) (emphasis added). The reason why FIG. 15 appears to flare at the end is because the conduit is bent downward at that location. Therefore, the Applicant respectfully contends that FIG. 15 of Clement does not disclose a “generally frusto-conically shaped” distal end portion as required by Claim 1.

In addition, the Applicant respectfully contends that Clement does not teach an “annular enveloping lip” as required by Claim 1. FIG. 15 shows a conduit having an elliptically-shaped blunt end. However, the enveloping lip of Claim 1 is annular in shape, i.e., it is toroidal or donut-shaped, and it is “sized to envelop and be engaged by a foreign body.” The distal end shown in FIG.15 of Clement is not circular, and it is not annular. Therefore, the Applicant respectfully contends that Clement does not disclose a distal end having “an annular enveloping lip” as required by Claim 1.

Furthermore, FIGS. 14 and 15 clearly disclose a conduit having two passageways. In an effort to further define Claim 1 over Clement, Claim 1 has been amended to now comprise a single passageway.

As such, Clement fails to disclose each and every element of Claim 1. Consequently, the Applicant respectfully requests the Examiner withdraw the rejection of Claim 1.

Applicant submits that Claim 1 is patentable over the prior art and in condition for allowance.

The Examiner rejected Claims 2-3 and 6-7 as anticipated by Clement. Those claims depend on Claim 1 and are patentable over Clement for the same reasons as Claim 1.

Therefore, the Applicant respectfully requests the Examiner withdraw the rejection of Claims 2-3 and 6-7. Applicant submits that Claims 2-3 and 6-7 are patentable over the prior art and in condition for allowance.

The Examiner also rejected Claim 9 as anticipated by Clement. Claim 9 is dependent upon Claim 1, and is therefore argued as not being anticipated by Clement for the same arguments as applied against the rejection of Claim 1. That is, FIG. 15 of Clement does not disclose the outwardly flaring frusto-conically shaped distal end, the annular enveloping lip, and the single passageway as required by Claim 1.

Additionally, in the rejection of Claim 9 the Examiner states that Clement discloses a lip being integrally formed with the distal end. However, the Applicant respectfully contends that Clement does not disclose as such. The Examiner cites the lip, or “tip,” of FIG. 28. However, the Applicant contends that the “tip” of FIG. 28 does not flare outwardly as required in Claim 1. Moreover, that “tip” is not disclosed as being integrally formed with the conduit. In supporting his rejection, the Examiner cites column 6, lines 24-29. However, this only states that the “conduit piece 220 [is] integrally formed from molded plastic with a valve body.” This does not discuss the “tip” of the conduit, which is the relevant claimed matter of Claim 9. The Examiner further cites column 7, lines 3-14 and column 2, lines 8-12. However, just as the case with column 6, lines 24-29, both of these cited portions only discuss the conduit and the valve body – not the “tip.” Moreover, not only does Clement not specifically state that the “tip” is integrally formed with the conduit, FIGS. 16-27 show a multitude of different “tips,” which may be configured to the end of the conduit.

As such, Clement fails to disclose each and every element of Claim 9. Consequently, the Applicant respectfully requests the Examiner withdraw the rejection of Claim 9. Applicant submits that Claim 9 is patentable over the prior art and in condition for allowance.

As to the rejection of Claim 10, Claim 10 is dependent from Claim 9, which is in turn dependent from Claim 1. Therefore Clement fails to disclose each and every element of Claim 10 for the reasons stated above. The Examiner argues that Clement discloses a first portion being formed from a hard material and a lip being formed from a flexible material. The Applicant respectfully contends that Clement does not disclose as such. The Examiner cites column 7, line 7, as disclosing a first portion, or “conduit,” (as labeled in Clement) that is made from a hard material. Yet, Clement states that “[a] *flexible* resilient polymeric material . . . can be formed into a conduit piece.” The Applicant contends that Clement itself states that the *conduit* is formed from a *soft* material – not a *hard* material as required by Claim 10.

As such, Clement fails to disclose each and every element of Claim 10. Consequently, the Applicant respectfully requests the Examiner withdraw the rejection of Claim 10. Applicant submits that Claim 10 is patentable over the prior art and in condition for allowance.

As to Claim 13, the Examiner has rejected Claim 13 as anticipated by Clement. In an effort to expedite and facilitate prosecution, and acting without prejudice, the Applicant has amended Claim 13. The currently amended Claim 13 now more clearly defines the frusto-conically shaped distal end as “flaring outwardly.” It also now claims a single passageway.

For the reasons set forth above, Clement does not have a frusto-conically shaped distal end that flares outwardly. In addition, it is clear that FIG. 15 does not disclose a single passageway. As such, Clement fails to disclose each and every element of Claim 13. Consequently, the Applicant respectfully requests the Examiner withdraw the rejection of Claim 13. The Applicant submits that Claim 13 is patentable over the prior art and in condition for allowance.

The Examiner rejected Claims 15-17 as anticipated by Clement. Those claims depend on Claim 13 and are patentable over Clement for the same reasons as Claim 13. Therefore, the Applicant respectfully requests the Examiner withdraw the rejection of Claims 15-17. Applicant submits that Claims 15-17 are patentable over the prior art and in condition for allowance.

The Examiner has also rejected Claim 19 as anticipated by Clement. Claim 19 is dependent upon 13, and therefore the rejection of Claim 19 should be withdrawn for the same reasons as applied to Claim 13. Additionally, Claim 19 is directed towards a lip being integrally formed with the distal end as found in Claim 9. Therefore, the Applicant respectfully contends that the rejection of Claim 19 should also be withdrawn for the same arguments as applied to the rejection of Claim 9. The Applicant submits that Claim 19 is patentable over the prior art and in condition for allowance.

Claim Rejections 35 U.S.C. 103

The Examiner has rejected Claims 4 and 5 under 35 U.S.C. § 103(a) as being obvious over Clement. 35 U.S.C. § 103(a) states that:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Applicant traverses the Examiner's rejections.

As to Claims 4 and 5, Applicant relies upon the previous argument hereinabove that FIG. 15 of Clement does not disclose: an outwardly flaring frusto-conically shaped distal end; an annular enveloping lip; nor a single passage as required by Claim 1. The Applicant submits that it would not have been obvious to one of ordinary skill in the art to modify Clement as such. Furthermore, FIG. 28 of Clement shows a frusto-conically shaped tip which flares *away* from the distal end, not *towards* it. As such, FIG. 28 teaches away from Claim 1.

Furthermore, the Applicant contends that it would not have been obvious to one of ordinary skill in the art to modify the device in Clement to have an annular enveloping lip. As stated above, the device in the present application and the device in Clement serve separate purposes, and there would be no reason to modify the device in Clement to have an annular enveloping lip because it is not used to envelop a foreign body. Rather, the purpose of the device in Clement is to supply and/or remove fluids.

The Examiner concedes that Clement does not disclose the claimed angular ranges of Claims 4 and 5. In addition, the Applicant contends that Clement does not disclose the claimed elements of Claim 1, nor would it have been obvious to one of ordinary skill in the art to do so. Therefore, since Claims 4 and 5 are dependent upon Claim 1, the Applicant

contends that it would not have been obvious to one of ordinary skill in the art to modify Clement to include all of the claimed elements found in Claims 4 and 5 because Clement lacks the requisite elements in the base Claim 1 upon which to substantiate an obviousness rejection.

The Applicant respectfully requests the Examiner withdraw the rejection of Claims 4 and 5. The Applicant submits that Claims 4 and 5 are patentable over the prior art and in condition for allowance.

The Examiner has rejected Claims 8, 12, 14, 18, and 20 as being obvious over Clement in view of U.S. Patent No. 4,380,998 to Kieffer, III et al.

Claims 8 and 12 are dependent upon Claim 1, and Claims 14 and 18 are dependent upon Claim 13. For the reasons argued above, Clement fails to anticipate Claims 1 and 3. Therefore the Applicant respectfully submits that Clement and Kieffer collectively fail to disclose each and every limitation of Claims 8, 12, 14, and 18. The Examiner's argument that it would have been obvious to one of ordinary skill in the art to combine the teachings of Clement and Kieffer lacks merit because Clement and Kieffer do not collectively teach the present invention. Modification of the references to meet the Applicant's claimed invention would not be obvious under 35 U.S.C. § 103. In addition, Kieffer does not add the deficiencies to the other reference necessary to negate the patentability of Claims 8, 12, 14, and 18. Accordingly, the Applicant respectfully requests the Examiner withdraw the rejection of Claims 8, 12, 14, and 18.

As to Claim 20, the Examiner contends that Clement discloses "a forward end being frusto-conically shaped and greater in diameter than the diameter of said central body

portion.” For the reasons stated above, the Applicant respectfully contends that Clement does not disclose a forward end as claimed in Claim 20.

The Applicant respectfully submits that Clement and Kieffer collectively fail to disclose each and every limitation of Claim 20. Therefore, the Examiner’s argument that it would have been obvious to one of ordinary skill in the art to combine the teachings of Clement and Kieffer lacks merit because Clement and Kieffer do not collectively teach the present invention. Modification of the references to meet the Applicant’s claimed invention would not be obvious under 35 U.S.C. § 103. In addition, Kieffer does not add the deficiencies to the other reference necessary to negate the patentability of Claim 20. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of Claim 20.

Lastly, the Examiner has rejected Claim 11 as being obvious over Clement in view of Kieffer, and in further view of Ehmsen. Claim 11 is dependent upon Claim 1. As stated above, Clement does not disclose the requisite elements of Claim 1 in order to substantiate a rejection under § 103 against Claim 11. The Applicant respectfully submits that Clement, Kieffer, and Ehmsen collectively fail to disclose each and every limitation of Claim 11. Therefore, the Examiner’s argument that it would have been obvious to one of ordinary skill in the art to combine the teachings of Clement, Kieffer, and Ehmsen lacks merit because Clement, Kieffer, and Ehmsen do not collectively teach the present invention. Modification of the references to meet the Applicant’s claimed invention would not be obvious under 35 U.S.C. § 103. In addition, neither Kieffer nor Ehmsen add the deficiencies to Clement


necessary to negate the patentability of Claim 11. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of 11.

It is respectfully submitted by this amendment that all bases of rejection and objection have been traversed and overcome. Thus, it is contended that in the absence of more pertinent art, the application has now been placed in a condition for allowance. A notice to this effect is, therefore, respectfully requested.

If the Examiner feels that prosecution of this application can be expedited, then he is courteously requested to place a telephone call to the Applicant's attorney at the number listed below.

Respectfully submitted,

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